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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,535	07/10/2000	George L. Murphy	AMBI:055US/MBW	9527

7590 11/19/2002

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EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT PAPER NUMBER

1637

DATE MAILED: 11/19/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

file

Office Action Summary	Applicant(s)	Applicant(s)
	09/613,535	MURPHY ET AL.
	Examiner	Art Unit
	Alexander H. Spiegler	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/13/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 49-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 and 53-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3,5,11</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-48 and 53-57) in Paper No. 10 is acknowledged. Applicant's state, "claims drawn to the inventions of Groups II and III are canceled from the present case", however, these claims have not been officially canceled in the proper amendment format. For the purposes of this examination, the claims of Groups II and III (claims 49-52) have been withdrawn from consideration, as being drawn to non-elected inventions.

Specification

2. The disclosure (pg. 29) is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 16, 48 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 16 is indefinite because it is not clear as to whether or not the one chain-terminating agent is involved in the extension. (i.e. It is not clear as to what is meant by having at least one chain-terminating agent "present" before or during each extension).

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B) Claims 48 and 56 are indefinite over “a Maxam and Gilbert treatment or variant thereof” because it is not clear as to what is meant by this recitation, and furthermore, the specification does not set forth a clear definition for this recitation.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-39, 43-48, 53, 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Recombinant Biocatalysts, Inc. (WO 98/01581, cited in the IDS), in view of Rosenthal (USPN 6,087,095).

Recombinant Biocatalysts teach a method creating a nucleic acid comprising;

a) annealing at least one primer nucleic acid to at least one template nucleic acid;

b) performing a first extension by extending the primer nucleic acid employing the template nucleic acid to form an extended nucleic acid;

c) denaturing the extended nucleic acid from the template nucleic acid;

d) annealing the extended nucleic acid to at least a second template nucleic acid;

e) performing a second extension by extending the extended nucleic acid employing the second template nucleic acid to form a twice extended nucleic acid;

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f) adding at least one chain terminating agent (i.e. a chain terminator), before or during at least one of the first or second extension, wherein said chain-terminating agent is incorporated into said extended nucleic acid (pgs. 8-9).

Specifically, the reference teaches that pooled polynucleotides may be subjected to random primer extension reaction or PCR amplification (pgs. 7-9) (steps a and b above). During these extension reactions the completion of the extension may be blocked or interrupted, creating collections of shorter or smaller polynucleotides (pools) and may hybridize with longer polynucleotides and initiate self-priming amplification (pgs. 7-9) (steps c-e above). The blocking or interrupting of the polynucleotides synthesis can be carried out with chain terminators (pg. 67) (step f above). This method can occur a plurality of times to produce a polynucleotide that encodes a protein of interest (pg. 6).

Additionally, the reference also teaches the various possibilities of the polynucleotides (e.g. lengths of polynucleotides) used, amplification conditions, etc. (pgs. 27-35).

Recombinant Catalysts does not teach the modifying or removing of the chain-terminating agent from the extended nucleic acid, if further extension is to be performed.

However, Rosenthal teaches that if additional cycles of extension are to be performed, Exonuclease III can be added to remove a chain terminator (col. 5-6). Rosenthal also teaches that preferred chain terminators are dideoxynucleotides (col. 5). Rosentahl also teaches that a Maxam Gilbert treatment can be used as a length-altering agent (col. 1), as well as phosphorothioate (col. 6-7 and Examples 1-9).

In view of the teachings of Rosenthal, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Recombinant Biocatalysts so as to have removed the chain terminators, in order to have achieved the benefit of providing additional cycles of nucleic acid extension for producing a plurality of polynucleotides that encode a polypeptide of interest.

7. Claims 40-42 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Recombinant Biocatalysts, Inc. (WO 98/01581, cited in the IDS), in view of Rosenthal (USPN 6,087,095), as applied to claims 1-39, 43-48, 53, 55-57 above, and in further view of Laney et al. (USPN 5,679,512).

The teachings of Recombinant Biocatalysts and Rosenthal are presented above. The references do not teach the incorporation of a ribonucleotide into the extension product.

However, Laney (col. 11) teaches that it is well known to have used polynucleotide primers comprising modified nucleotides at the 3' end of the polynucleotide primer (i.e. that would be incorporated into an extension product), said modified nucleotides comprising, phosphorothioates, methylated bases, and ribonucleotides.

In view of the teachings of Laney, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the methods of Recombinant Biocatalysts and Rosenthal so as to have included the steps of incorporating modified bases into the 3' end of a polynucleotide primer, in order to have achieved an equally effective benefit of nucleic acid extension.

Conclusion

8. No claims are allowable.

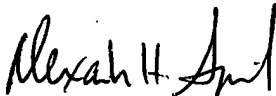
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Correspondence

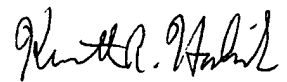
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Alexander H. Spiegler
November 18, 2002



KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

11/18/02